

Complete Summary

GUIDELINE TITLE

Evidence-based care guideline for prevention of thromboembolism after cavopulmonary anastomosis (bidirectional Glenn and Fontan operations).

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence-based care guideline for prevention of thromboembolism after cavopulmonary anastomosis (bidirectional Glenn and Fontan operations). Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2006 May. 14 p. [34 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for prevention of thromboembolism after cavopulmonary anastomosis (bidirectional Glenn and Fontan operations). Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 May 29. 10 p.

Once the guideline has been in place for four years, the development team reconvenes to explore the continued validity of the guideline. This phase can be initiated at any point that evidence indicates a critical change is needed.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [August 16, 2007, Coumadin \(Warfarin\)](#): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.
- [October 6, 2006, Coumadin \(warfarin sodium\)](#): Revisions to the labeling for Coumadin to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Thromboembolism after cavopulmonary anastomosis

GUIDELINE CATEGORY

Evaluation

Prevention

Risk Assessment

Treatment

CLINICAL SPECIALTY

Cardiology

Critical Care

Pediatrics

Surgery

INTENDED USERS

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

To provide a guideline for the effective prevention of thromboembolism after cavopulmonary anastomosis

TARGET POPULATION

These guidelines are intended for use in infants and children who have undergone the bidirectional Glenn or modified Fontan operation.

The guidelines do not address all considerations needed to manage those with the following:

- Coagulopathy
- Salicylate allergy

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Preoperative history and physical exam, including family history or physical findings suggestive of coagulopathy
2. Laboratory evaluation, including preoperative complete blood count (CBC) with platelets and coagulation studies if abnormalities suspected

Prevention/Treatment

1. Antithrombotic aspirin therapy
2. Warfarin therapy in high-risk patients
3. Alternative antithrombotic therapy when aspirin therapy is temporarily contraindicated

MAJOR OUTCOMES CONSIDERED

- Intravascular and/or intracardiac thrombus formation and thromboembolic complications
- Hemodynamic stability
- Length of stay in the Cardiac Intensive Care Unit (CICU)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To select evidence for critical appraisal by the group for the update of this guideline, the Medline, EmBase and the Cochrane databases were searched. Evidence from 2000 and before was verified for inclusion in the guidelines. Evidence from 2001 to the January, 2006 were reviewed to generate an unrefined, "combined evidence" database using a search strategy focused on answering clinical questions relevant to prevention of thromboembolism or anticoagulation following cavopulmonary anastomosis and employing a combination of Boolean searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on searching on human-indexed thesaurus terms (MeSH headings using an OVID

Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. The citations were reduced by: eliminating duplicates, non-English articles, and adult articles. The resulting abstracts were reviewed by a methodologist to eliminate low quality and irrelevant citations. During the course of the guideline development, additional clinical questions were generated and subjected to the search process, and some relevant review articles were identified. December, 2000 was the last date for which literature was reviewed for the previous version of this guideline. The details of that review strategy are not documented. However, all previous citations were reviewed for appropriateness to this revision.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using a grading scale, and examined current local clinical practices.

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference and clinical expertise. During formulation of these guidelines, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Experience with the implementation of earlier publications of this guideline has provided information which has been incorporated into this revision.

The guidelines have been reviewed by clinical experts not involved in the development process, senior management, and other individuals as appropriate to their intended purposes. The guideline is based in part on three independent reviews performed by members of Evidence-Based Care Group of Health Policy & Clinical Effectiveness at Cincinnati Children's Hospital and Medical Center (CCHMC) using AGREE criteria (Appraisal of Guidelines for Research and Evaluation).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is followed by evidence grades identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

Assessment

1. Preoperative history and physical exam

- Patient or family history of coagulopathy, salicylate allergy, or viral exposures
- Physical findings suggestive of coagulopathy (e.g., petechiae, purpura)

2. Laboratory assessment

- Preoperative complete blood count (CBC) with platelets
- Coagulation studies if history or physical suggests abnormalities and prior to initiation of warfarin

Note: Available evidence does not support routine screening for coagulopathies.

Treatment Recommendations

1. **It is recommended that patients begin antithrombotic aspirin therapy upon resuming oral intake following the bidirectional Glenn or Fontan operation.** (Jacobs et al., 2002 [C/D]; Barker et al., 2005 [D]); Local Expert Consensus (E))

Note: Both aspirin and warfarin reduce the risk of thromboembolism. Although the choice of pharmacologic regimen remains controversial, the risk of hemorrhagic complications in children, compounded by the difficulties of monitoring and maintaining appropriate anticoagulation on warfarin, favors the use of aspirin for antithrombotic therapy (Barker et al., 2005 [D]). The two appear equivalent in the prevention of myocardial infarction and stroke in the setting of atherosclerosis (Anand & Yusuf, 1999 [M]); however, in pediatric and adult populations, the risk of hemorrhagic complications is higher with warfarin therapy (Anand & Yusuf, 1999 [M]; Hart et al., 1999 [M]; Rao et al., 1989 [D]; Bradley et al., 1985 [D])

2. **It is recommended that warfarin therapy be considered in patients at higher risk due to the following factors:**

- Previous thromboembolic complications (Kaulitz et al., 2005 [D])
- Poor ventricular function (Kaulitz et al., 2005 [D]; Al-Khadra et al., 1998 [D])
- Extracardiac Fontan connections (Shirai et al., 1998[D]; Petrossian et al., 1999 [E]; Laschinger et al., 1996 [E])
- Pulmonary stump (Oski et al., 1996) [D])
- Atrial tachyarrhythmias (Cheung et al., 2005; Kaulitz et al., 2005 [D])

Note: Children with Fontan operations require a lower warfarin dosage than children receiving warfarin after other types of congenital heart surgery for a similar degree of anticoagulation (Streif et al., 1999 [C]). The recommended starting dose is 0.1 mg/kg to maintain a target international normalized ratio (INR) range of 2.0 to 3.0.

3. **It is recommended that alternative antithrombotic therapy be considered during periods when aspirin therapy is temporarily contraindicated (reference See note).**

Note: Examples of aspirin contraindications may include exposure to influenza or varicella, receipt of varicella vaccine (American Academy of Pediatrics, 2003 [O]), and elective surgical or dental procedures associated with bleeding. Risks of discontinuation of aspirin versus the risk of Reye's syndrome or bleeding associated with dental or surgical procedures must be considered by the clinician and family on an individual basis.

Definitions:

Evidence Based Grading Scale

M: Meta-analysis or systematic review
A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
D: Retrospective analysis

S: Review article
O: Other evidence
E: Expert opinion or consensus
F: Basic laboratory research
L: Legal requirement
Q: Decision analysis
X: No evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and classified for each recommendation (see "Major Recommendations") using the following scheme:

Evidence Based Grading Scale:

M: Meta-analysis or systematic review
A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
D: Retrospective analysis
S: Review article
O: Other evidence
E: Expert opinion or consensus
F: Basic laboratory research
L: Legal requirement
Q: Decision analysis
X: No evidence

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased risk of intravascular and/or intracardiac thrombus formation and thromboembolic complications

POTENTIAL HARMS

- Risk of hemorrhagic complications is higher with warfarin therapy than with aspirin therapy
- There is a risk of Reye's syndrome with aspirin therapy

CONTRAINDICATIONS

CONTRAINDICATIONS

Potential temporary contraindications for aspirin therapy in the following patients:

- Exposure to influenza or varicella or receipt of varicella vaccine
- Elective surgical or dental procedures associated with bleeding

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Unfortunately, although the problem of thromboembolism has been recognized, clinicians have not systematically evaluated the use of antithrombotic therapy. A controversy exists with respect to the most appropriate choice of pharmacologic regimen. To date, no prospective, randomized controlled trials have addressed this question. Monotherapy with either aspirin or warfarin is most commonly implemented. In developing this guideline, the working group recognized the paucity of large-scale studies with direct bearing on this particular pediatric population.
- The specific recommendations in this guideline are drawn from directly applicable studies where possible, but are largely extrapolated from smaller studies and from studies more indirectly related to the present issues.
- These recommendations result from review of literature and practices current at the time of their formulations. This guideline does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this guideline is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Appropriate companion documents have been developed to assist in the effective dissemination and implementation of the guideline.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 May 29 (revised 2006 May)

GUIDELINE DEVELOPER(S)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

GUIDELINE COMMITTEE

Cardiac Guideline Development Team 2006

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

This guideline was developed without external funding.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Cincinnati Children's Hospital Medical Center Web site](#).

For information regarding the full-text guideline, print copies, or evidence based practice support services contact the Children's Hospital Medical Center Health Policy and Clinical Effectiveness Department at HPCEInfo@chmcc.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Going home after heart surgery. Home care. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Dec. 1 p. Available in English and Spanish from the [Cincinnati Children's Hospital Medical Center Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on March 11, 2004. The information was verified by the guideline developer on December 19, 2006. This summary was updated by ECRI on March 6, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin sodium). This summary was updated by ECRI Institute on September 7, 2007 following the revised U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin).

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